



STATE OF DELAWARE  
DEPARTMENT OF ADMINISTRATIVE SERVICES  
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DELAWARE STATE BOARD OF PHARMACY  
JESSE S. COOPER BUILDING, ROOM 205  
FEDERAL AND WATER STREETS  
DOVER, DELAWARE 19901

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July 23, 1998

Dockets Management Branch (HFA-305)  
Food & Drug Administration  
12420 Parklawn Drive, Room 1-23  
Rockville, MD 20857

To Whom It May Concern:

**RE: FDA proposed rules on off-label uses**

The Delaware Board of Pharmacy has received your correspondence regarding proposed rules allowing greater flexibility for manufacturers to disseminate information about the safety, effectiveness or benefits of "off-label" uses for marketed drugs, biologicals and medical devices. The Delaware Board of Pharmacy feels that the new proposed rules are not warranted. The Board has concerns that disseminated information may be false and misleading, may be disseminated inappropriately and would pose a significant risk to public health. The Board further feels that the current practice allows for the appropriate and best way of handling off-label uses of medications.

Sincerely,

David W. Dryden, R.Ph., J.D.  
Executive Secretary

DWD/fpw      Dockets, FDA

Cc: Mary Lou Hurd, Board President  
Carmen Catizone, NABP, Executive Director  
Jim Warren, FDA Wilmington Branch  
File

98N-0222

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DELAWARE BOARD OF PHARMACY

JESSE COOPER BLDG, ROOM 205

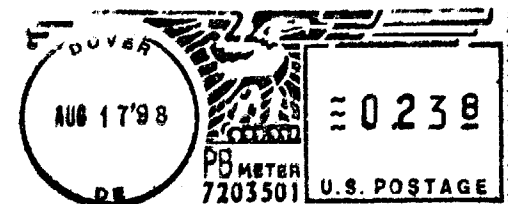
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